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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,747	03/14/2000	Alberto Reiner	622-39	8132

7590 06/18/2002

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EXAMINER
OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
1623	4

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/524,747	REINER ET AL.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Granger, EP 466650.

Claims 1-12 are drawn to a pharmaceutical formulation for oral use containing diclofenac in acid and/or salt form together with alkali metal bicarbonates in which the alkali metal bicarbonates are present in an amount of from 20 to 80% by weight of diclofenac.

Claims 13-19 are drawn to a method for obtaining an average Cmax of Diclofenac via administration of diclofenac in acid and/or salt form together with alkali metal bicarbonates in which the alkali metal bicarbonates are present in an amount of from 20 to 80% by weight of diclofenac.

Claims 20-26 are drawn to a method for obtaining an average Cmax of Diclofenac via administration of diclofenac in acid and/or salt form together with alkali metal bicarbonates in which the alkali metal bicarbonates are present in an amount of from 20 to 80% by weight of diclofenac.

Granger anticipates claims 1-12 as it teaches a pharmaceutical formulation comprising a non-steroidal anti-inflammatory and a metal base or basic salt such as hydroxide, sulfate, carbonate, bicarbonate, subcarbonate, or trisilicate; wherein the nonsteroidal anti-inflammatory may be diclofenac and the alkali metal can be aluminum, sodium, magnesium, potassium or bismuth (pp. 1 and 2). Granger further discloses that the metal base or basic salt may be administered in an amount ranging from about 25 to about 100% (p.2, line 57 - p.3, line 5).

Granger also teaches that the pharmaceutical formulation or composition comprising the non-steroidal anti-inflammatory agent such as dicoflenac may be administered in admixture with suitable pharmaceutical diluents, excipients or carriers and that the active drug components may be combined with any oral nontoxic pharmaceutically acceptable inert carrier such as lactose, starch, sucrose, etc. Furthermore, that sweetening and flavoring agents and preservatives can also be included where appropriate (p. 3, lines 6-23) anticipating the presence and amount of at least one flavoring substance, be it mint, aniseed and ammonium glycyrrhizinate as these flavoring substances could be adjusted in proportion to suit an appropriate taste. Granger also teaches the use of disintegrating agents such as methylcellulose and cross-linked PVP (p.3, lines 16-23) which anticipate the use of immediate and delayed release layers.

Granger discloses that the metal base or basic salt is co-administered with fenamic acid derivatives or non-steroidal systemic anti-inflammatory agents to confer a cytoprotective effect or reduce the gastrointestinal inflammation associated with administration of these agents (p.2, lines 20-58).

Although Granger does not explicitly teach the T_{max} and C_{max} values, the T_{max} and C_{max} values are a function of administering the diclofenac with the metal base or basic salt wherein the concentration of the metal base or basic salt is 20-80% by weight; thus, given that Granger teaches administration of diclofenac or fenamic acid derivatives with a metal base or basic salt wherein the concentration of the basic salt is analogous to that of applicant, 25%-100%, the T_{max} and C_{max} values would be inherently achieved (see *Ex parte Nowitzki*).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600